# Best Practices for Reducing, Refining, and Replacing Animal Use for Regulatory Safety Testing

## January 18-20, 2011
## William H. Natcher Conference Center - Bethesda, MD

The development, validation, and application of new safety testing methods for hazard identification and risk assessment remains an important priority for scientists in industry, government, and academia. Substantial progress has been made in recent years towards the development, validation, and regulatory acceptance of alternative test methods that reduce, refine (less pain and distress), and replace the use of animals for safety testing. Over 30 alternative test methods have been accepted or endorsed by U.S. regulatory agencies.

While toxicologists recognize the utility and strengths of these new approaches, many are unfamiliar with the specific techniques. In order to implement the use of a new test method, it is important to familiarize the regulated community with the method, as well as the manner in which agencies expect the method to be conducted and data interpreted. Both users and regulatory agency staff need to become familiar with the technical procedures required to conduct the new method, and to understand the method's usefulness and limitations. Consequently, there is a need for in-depth training of individuals in the safety and regulatory community on the appropriate use of new tools for hazard, safety, and risk assessments.

This workshop brings together scientific experts representing relevant stakeholder organizations. Participants will learn the strengths and weaknesses of available alternative test methods, become familiar with the types of data they provide, and learn how to use these data in hazard, safety, and risk assessments.

### Workshop Objective

The primary objective of the workshop is to assist participants in gaining a practical understanding of the theory and application of available alternative methods for each the following regulatory safety testing areas: 1) ocular corrosion and severe irritation; 2) skin sensitization, and 3) acute systemic toxicity.

The specific goals of the workshop are to:

1) Provide an overview of the available methods, including the applications, strengths and weaknesses of each method.
2) Provide information on the procedures for conducting and interpreting data in accordance with regulatory testing requirements and guidelines.
3) Allow an opportunity to become familiar with data generated by each test method.
4) Provide a forum for scientists to share information on the appropriate use of results in regulatory safety testing.
5) Discuss challenges of incorporating alternative test methods into regulatory safety testing guidelines
6) Identify and discuss new methods in the development and validation pipeline for each safety testing area, and ways to increase the availability of high quality data necessary for validating new methods.

**Who Should Attend**

Scientists from industry, government, and academia that have an interest in learning more about the available alternative test methods for ocular corrosion/severe irritation, skin sensitization, and/or acute oral systemic toxicity are encouraged to participate.

**Workshop Program**

The workshop will begin on [INSERT DATE], and will conclude at approximately 5:00 p.m. on [INSERT DATE]. A keynote address will detail the U.S. requirements for the consideration of available alternative test methods. Each day will be devoted to available alternative methods for one of the regulatory safety testing areas listed above. Each day's program will begin with some background information on the scientific development of the assay and discussion of the regulatory status of the assay. The program will also include practical instruction on application of the assay including standard protocols and data interpretation.

Workshop participants will also have an opportunity to apply knowledge gained from that day's program during case study exercises.